

THE REGULATORY REGIME AND ITS IMPACT ON INNOVATION ACTIVITIES IN AGRO-FOOD BIOTECHNOLOGY IN THE EU AND USA

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biotechnology in the EU and USA

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Abstract

In recent years the development of agro-food biotechnology significantly differed between the EU and the USA. While in the EU a quasi-moratorium was agreed on in 1999 preventing the commercial cultivation of transgenic crops in the EU, such plants are produced on millions of hectares in the USA and other parts of the world. This paper aims to give some insight in the effects of this differing situation on innovation activities in the field of agro-food biotechnology in the two regions.

Firstly, the paper gives a brief overview on regulatory principles and implementation activities in the field of agro-food biotechnology in the EU in comparison to the US system. Based on this background the development of specific indicators for innovation activities in this field is compared for the EU and the USA. This relates e. g. to the character of research projects in the laboratory phase, scientific publications in this field, the deliberate release of genetically modified plants, the approval of such plants and the cultivation of transgenic crop in commercial agriculture. In addition, the relevance of additional factors for innovation activities in agro-food biotechnology in the EU is analysed in this paper. Finally some conclusive general remarks are drawn concerning the impacts of differing regulatory systems on innovation activities taking into account the experiences in other fields related to food production and food processing (e. g. Functional food, organic farming and food processing).

The regulatory regime and its impact on innovation activities in agro-food biotechnology in the EU and USA

Since the mid 1990s genetically modified (GM) plants are marketed and cultivated which directly or via animal feed can enter the food chain. In this respect genetic engineering approaches are regarded by their protagonists as major tools to increase productivity and efficiency in food processing in future (Garza & Stover, 2003). On the other hand, an intensive public debate is carried out globally concerning the safety of these approaches and derived novel foods as well as their socio-economic impacts (Otsuka, 2003). Critics of genetic engineering see the potential that this technology may result in harm for the environment and human or animal health. In addition, the wider impacts of the use of genetic engineering in the agro-food sector on society as a whole are often questioned in the public debate (Menrad, Gaisser, Huesing, & Menrad, 2003).

1 Regulatory principles in EU and USA

Since GMOs and derived novel food products represent new developments in the area of food production and food processing, there have been relatively restricted experiences with this type of products. Therefore, state authorities which are generally in charge to ensure safety of consumers in relation to nutrition as well as to prevent misleading of consumers in this field took specific activities to deal with potential risks of GMOs related to human health and the environment. The general targets of the respective legislation are to ensure human health when consuming GMOs or derived novel foods, to prevent or minimise potential harm of GMOs to the environment as well as to provide the necessary information in order to ensure the freedom of choice of consumers or users of such products. In particular, the EU policy related to GMOs was intensively influenced by the emergence of the BSE and other food crises during the 1990s, the public criticism and undermined trust in public authorities to adequately manage such crises in the sensitive area of food production

and food processing as well as the low consumer acceptance of agro-food biotechnology (Loureiro, 2003).

The fundamental question which arises concerning regulation of GMOs is whether GM crops or other GMOs have to be acknowledged like conventional crops or organisms, and therefore it is sufficient to use the general legislation valid for such crops or organisms or whether it is necessary to adopt different and specific regulations for GMOs. In this context USA and EU have decided to take divergent approaches. In the USA GM crops are considered specific and different in terms of intellectual property rights since a patent can be granted to them but not to conventional crops. On the other hand, the introduction of GM crops in the environment and into the market follows the principle of “substantial equivalence” and therefore the same steps are required like for conventional crops (Esposti & Sorrentino, 2002).

The EU takes the opposite approach concerning regulation of GMOs compared to the USA. Even after Directive 98/44/EC patents cannot be granted to GM crops. They are protected by the same breeders rights acknowledged to conventional crops, thereby giving higher priority to the “farmers rights” and “breeders privilege” than to the innovators’ intellectual property rights (Esposti & Sorrentino, 2002). In contrast to the US approach, the EU approach for environmental release and market approval of GMOs follows a rather strict interpretation of the “precautionary principle”, i. e. specific regulations have been put into force dealing with GMOs which require different and often more complex procedures than for conventional products.

2 Implementation of regulation in the EU

GMOs have been regulated by the EU since the beginning of the 1990s. The EU Directive on the contained use of genetically modified organisms (Directive 90/219/EEC) and on deliberate release of genetically modified organisms (Directive 90/220/EEC) were the first regulations which tried to establish a system for controlling R&D and commercialisation of GMOs in the EU. These regulations were designed to protect citizens’ health and the

environment, and addressed authorisation, labelling and traceability issues relevant for GMOs. Directive 90/220/EEC covered the deliberate release of GMOs into the environment for R&D purposes as well as commercialisation of such organisms. In contrast to the US regulation the EU Directive takes a preventive approach emphasising prior assessment and approval of GMOs. One main element of this Directive constitutes that an environmental risk assessment has to be carried out before any experimental or commercial release of GMOs into the environment. For market approval of GMOs a two-step procedure is foreseen in this Directive: first the competent authority in a Member State has 90 days either to forward the notification dossier to the European Commission with a favourable opinion or to inform the notifier that the proposed commercial release does not fulfil the requirements of the Directive (Huffman & Tegene, 2002). Afterwards, a EU-wide risk assessment procedure takes place in which all Member States can raise objections concerning the notification (Menrad et al., 2003).

Since its enactment in the year 1990 Directive 90/220/EEC was criticised by different stakeholder groups. In addition, all notifications for market approval of agricultural GMOs raised concerns of one or several EU Member States during the 1990s (Sauter & Meyer, 2000). Therefore, in June 1999 a de facto moratorium on commercialisation of GMOs was agreed by the Community's Council of Environmental Ministers to suspend all approval applications for GMOs until implementation of the revised Directive 90/220/EEC, in order to provide a more strict legal framework covering not only safety issues but also labelling and traceability of GMOs (Lheureux et al., 2003).

Specific rules on GMOs for human consumption were introduced in EU Regulation 258/97/EC on Novel Foods and Novel Food ingredients which came into force in 1997. This Regulation distinguishes six categories of novel food products of which two refer directly to products derived from GMOs (European Commission, 1997). In contrast to traditional food products, novel foods are subject of pre-market approval in the EU. In order to ensure the consumers right to information and freedom of choice, EU legislation mandates labelling to indicate the presence of GMOs which was laid down in article 8 of Regulation 258/97/EC.

According to this article “additional specific labelling requirements shall apply to foodstuffs... which renders a novel food or food ingredient no longer equivalent to an existing food or food ingredient. A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics” (European Commission, 1997). However, the linking of labelling requirements of GMOs with the rapidly developing analytical tools for such organisms has lead to serious implementation problems in nearly all Member States of the EU (Sauter & Meyer, 2000).

After five years of intensive discussion Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms was passed in February 2001 (European Commission, 2001) which replaced Directive 1990/220/EEC. A commercial approval of GMOs will be given only for a ten-years time period and can be extended for another ten years. In addition, starting with the year 2005 no commercial release of GMOs will be allowed which contains antibiotic resistance marker genes, for which harmful impacts on human health and the environment are discussed (Schütte, Stirn, & Beusmann, 2001). Directive 2001/18/EC requires a post-market monitoring of each approved GMO in order to detect unanticipated effects of such organisms to the environment and human health. Furthermore, labelling of GMOs is foreseen in this Directive without giving details concerning traceability requirements for products which contain GMOs or are derived from GMOs (Loureiro, 2003). The same relates to tolerance levels for unadventitious mixture of GM material with non-GM crops or products (Menrad et al., 2003).

In November 2003 the Regulation on genetically modified food and feed (Regulation 1829/2003/EC) came into force (European Commission, 2003a) which partly replaced the Novel Foods Regulation. In the 1829/2003 Regulation it is foreseen that notifications for market approval of food and feed products produced from GMOs have to be delivered to a central authority within the EU, i. e. the newly established European Food Safety Agency

(EFSA). Learning from the US experience with Starlink, the Regulation provides that GMOs likely to be used as food and feed can only be authorised for both purposes or not at all. Concerning labelling of GM derived foods the Regulation extends the labelling requirements of Regulation 258/97/EC to all foods produced from GMOs, irrespectively of whether there is DNA or protein of GM origin in the final food product or the feed. This means that the use of genetic engineering approaches at any step of the food production and processing process will lead to labelling requirements even if GMOs cannot be identified in the final product (like e. g. in soybean oil). Such a system requires the establishment of a traceability system for GMOs in the food processing chain as well as the delivery of information to whom and from whom GM foods are made available (Menrad et al., 2003). The labelling requirement will not apply for adventitious presence of GMOs approved for commercialisation in the EU below a 0.9 % threshold. Products which have not received permission to be marketed in the EU, but for which the scientific assessment is positive, will have to be labelled if the GM content exceeds 0.5 % adventitiously (Kinderlerer, 2003).

In July 2003 the European Commission has published guidelines for developing strategies and best practices to ensure the co-existence of GM crops with conventional and organic agriculture (European Commission, 2003b). They are intended to support Member States to develop workable measures for co-existence in conformity with EU legislation. The guidelines set out the general principles as well as the technical and procedural aspects which should be taken into account during this process. In the guidelines it is underlined to ensure a fair balance between the interests of farmers of all types of production, i. e. farmers should be able to choose the production type they prefer. During the phase of introduction the European Commission proposed the general principle that farmers who introduce a new production type should be responsible for implementing the measures necessary to limit admixture during the phase of introduction of a new production type in a region (European Commission, 2003b).

3 Impact of regulation on innovation indicators in the EU

The impact of the regulatory framework relevant for agro-food biotechnology and genetic engineering in the different regions can be analysed on various levels. In the following respective data are presented for the areas of scientific research, field trials with GMOs, approval and cultivation of GMOs in the different regions.

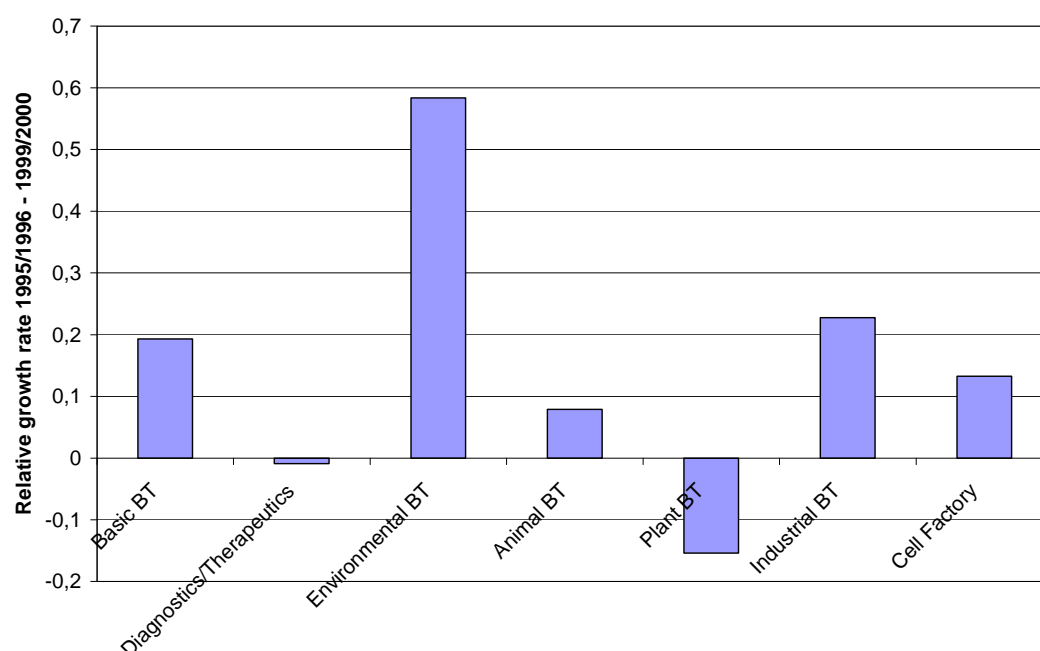
In the EU there is still a broad pipeline of **R&D activities related to agricultural and food GMOs** which is fuelled by differing organisations like large multinational companies, SMEs, universities and non-university research institutions (Lheureux et al., 2003). In the EU a broad variety of different plants are used for genetic modification experiments, with model plants (*Arabidopsis thaliana* and tobacco), vegetables (including mainly potatoes and tomatoes), cereals (like e. g. maize, wheat, barley) and specific field crops (in particular oilseed rape, sugar beet) accounting for more than 80 % of all GM projects in the laboratory phase (Lheureux et al., 2003). Other crop categories like fruits, (wood) trees, grasses or flowers are of minor importance in the EU.

So-called input agronomic traits account for 38 % of all genetic modification projects in the laboratory phase (Lheureux et al., 2003). Resistance against herbicides, insects and other plant pathogens are investigated in 21 % of all projects. Around 13 % of all identified projects deal with abiotic stress or the improvement of yield characteristics of plants. Output traits account for 39 % of all traits with half of the projects referring to modification of specific nutrients or ingredients (Lheureux et al., 2003). The output trait category “health-related ingredients” plays an important role as well, since it accounts for 11 % of all projects related to GM plants in the laboratory phase. 17 % of all projects are classified in the “marker/other traits” category including projects in a very early phase of the development of a GM plant (Lheureux et al., 2003).

Another indicator for research activities in a specific area are scientific publications in reviewed journals. The analysis of **publication activities in biotechnology** in the EU Member States indicates a strong growth of the scientific output in biotechnology between 1991 and 2000 in all countries (Reiss & Dominguez Lacasa, 2003). In addition, the

significance of biotechnology among all scientific activities in the Member States increased during the recent decade with most European countries performing above the world average. However, the analysis of the dynamics of specialisation patterns in biotechnology-related publications indicates that the area of plant biotechnology is the only sub-field of biotechnology research which showed significant negative growth during the second half of the 90s in the EU (figure 1).

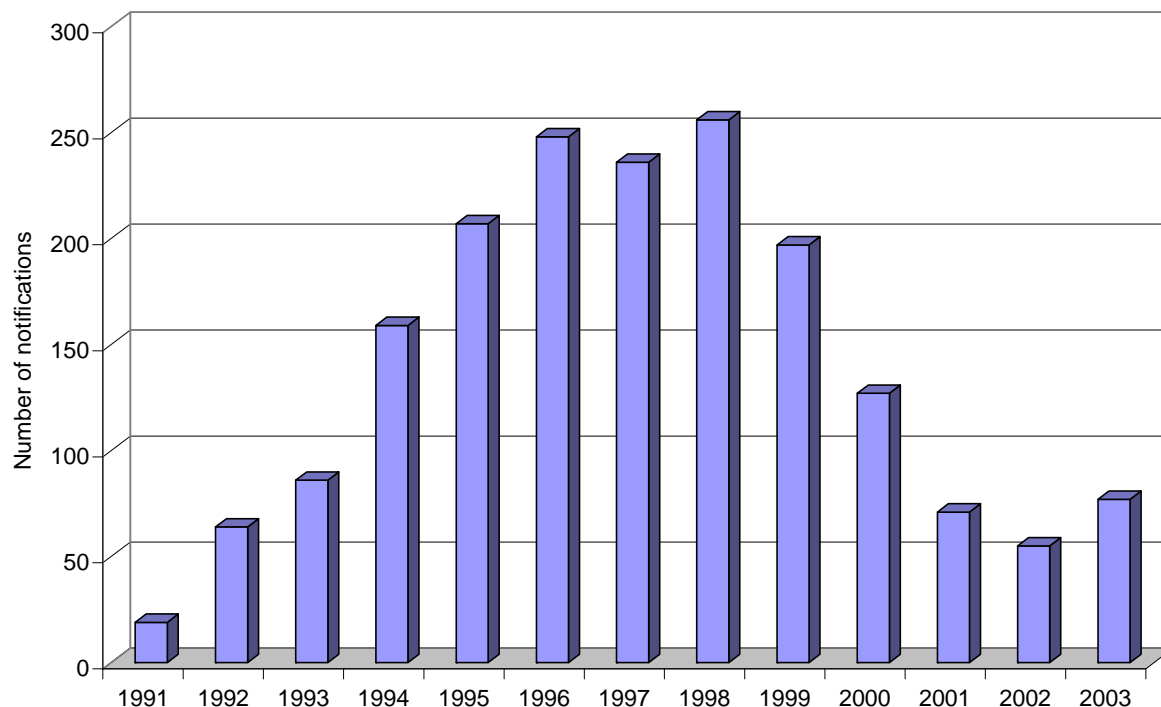
Figure 1: Specialisation trends in biotechnology across EU between 1995 and 2000



Source: Reiss & Dominguez Lacasa, 2003

Based on the analysis of an EU database on **field trials with GM plants** it can be realised that the number of notifications for GMO field trials increased rapidly between 1991 and 1997 to reach a peak in 1998 and declined rapidly afterwards to the level at the beginning of the decade. In 2001, there were no more than 61 notifications for field trials with GM plants with a small recovery in recent two years (figure 2). This strong decrease can be interpreted as a reaction of EU industry and research institutes to the 1999's decision on the de facto moratorium on GMOs in the EU.

Figure 2: Number of field trials notifications with GM plants in the EU between 1991 and 2003



Source: Lheureux et al., 2003, Transgen, 2004

The majority of EU field trial notifications with GM plants referred to four crops: maize (26.4 %), oilseed rape (20.9 %), sugar beet (15.6 %) and potato (11.4 %) (Lheureux et al., 2003), while other crops like tomatoes, tobacco, chicory, vegetables, cotton, fodder beet and wheat ranked between 4.2 % and 1.1 %. The proportions of the main crops have not changed significantly between 1993 and 2001, but the total number of notifications has decreased dramatically, showing a decline in all major crops since 1999 (Lheureux et al. 2003). Over the whole period between 1991 and 2001, resistance traits against pathogens, insects and herbicides were predominant in field trial notifications (around 60 % of all notifications). Herbicide resistance accounted for 42 % of all notifications followed by insect resistance with 11 % and resistance against other pathogens with 13 %. Output traits accounted for 19 % of all EU field trials between 1991 and 2001 showing an increase in the importance of output traits until the mid 1990s. Afterwards a relatively steady decline of the

percentage of output traits was registered reaching a level of 12 % of all field trial notifications in 2001 (Lheureux et al., 2003).

Since due to the de facto moratorium in 1999 no **market approval for GM plants** have been granted in the recent years, a number of applications are still pending approval. According to the EU Commission, 14 GM crops and 4 GM products for pharmaceutical use (vaccines, testkits) have been approved for commercialisation so far (European Commission, 2004). Approvals for GM plants concern maize, oilseed rape, carnation, chicory, soybean and tobacco. Concerning traits, herbicide resistance is predominant among the approved GM plants (European Commission, 2004). At the beginning of 2004, 22 GM products are pending approval under Directive 2001/18/EC (European Commission, 2004).

Due to the running de facto moratorium the commercial planting of GM in the EU is very limited. The major exception is the cultivation of one variety of insect-resistant maize (the variety *Compa CB* (Bt 176) from Syngenta Seeds) which was approved by the European Commission for planting in 1998 (before the moratorium) and has been taken up on a commercial basis in Spain. In this year Bt maize was first planted commercially in Spain on around 20,000 to 25,000 hectares (Brookes, 2003). Until 2002 the cultivation area of Bt maize remained at this level (which equals to around 4 % to 5 % of the cultivation area of maize in Spain) because of a voluntary arrangement of Syngenta Seeds to limit seed availability until the EU moratorium is lifted. In 2003 the cultivated area with Bt maize was increased to 32,000 hectares in Spain (James, 2003). Besides field trials with GMOs or plantings in the context of research projects to analyse gene flow of GM plants (which are carried out in different EU Member States like United Kingdom, Germany, Denmark), no commercial cultivation of GM plants exists in other EU Member States (Lheureux et al., 2003).

4 Factors influencing potential commercialisation of GMOs in the EU

The outcome of a 2003 finished research project financed by the European Commission indicates that 39 % of institutions active in agro-food biotechnology related

research have cancelled R&D projects related to GMOs in the last four years (Lheureux et al., 2003). While less than one quarter of the universities or public research institutes have cancelled GMO projects, more than half of the SMEs and two third of the large companies reported such activities (table 1).

Table 1: Cancelling of R&D projects related to GMOs in the last four years

Institution	Number of respondents	GMO projects cancelled	
		Yes	No
SME	33	54.5 %	45.5 %
Large company	28	67.5 %	32.5 %
University institutes	44	25.0 %	75.0 %
Public research institutes	37 ¹⁾	21.6 %	75.1 %
Total	165 ²⁾	38.8 %	60.6 %

¹⁾ One respondent answered "Don't know"

²⁾ Other institutions are included, 3 questionnaires without an answer to this question.

Source: Lheureux et al., 2003

A broad range of different reasons was mentioned by the respondents for cancelling R&D projects related to GMOs in the agricultural field. The highest importance was given to the regulatory field (e. g. unclear legal situation in the EU, unclear or high requirements for safety testing of products), and the uncertain market situation due to low consumer and user acceptance of GM products. Between 16 % and 21 % of all respondents marked these two aspects (Lheureux et al., 2003). In addition, a relatively high importance was given to financing and cost aspects as well as the feasibility of the planned R&D projects, while intellectual property right issues, an appropriate co-operation partner as well as experienced

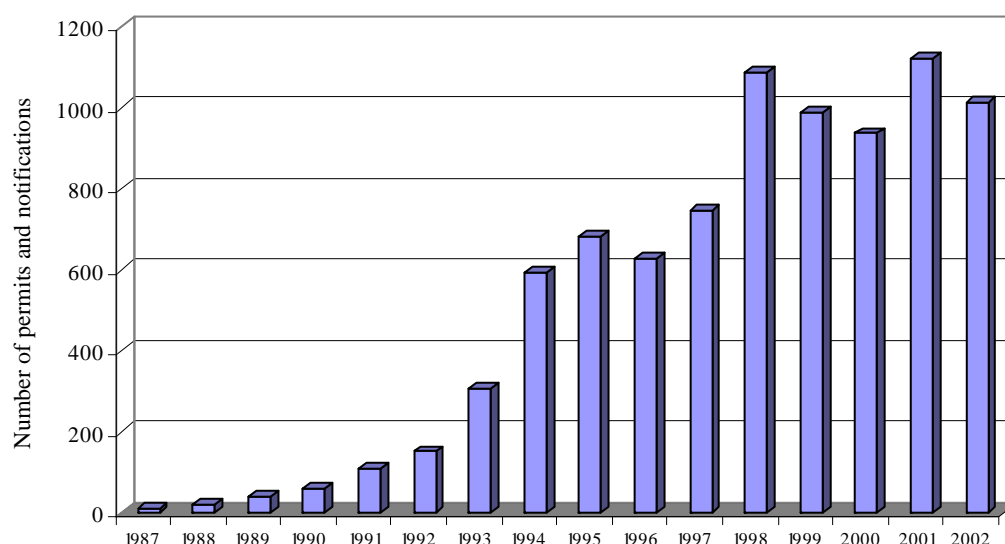
staff was only for a small group of respondents a reason for cancelling R&D laboratory projects related to GMOs (Lheureux et al., 2003).

5 Impact of regulation on innovation indicators in the USA

Comparable data to the character of GMO-related research projects to those of the EU could not be found during literature search for USA. Therefore, the analysis for this country starts with field trials with GM plants.

In the US, over 8,400 **field trials with GMOs** have been registered since 1987 (figure 3). A direct comparison between the numbers of notifications in the EU and the number of notifications in the USA is not feasible due to differences in how the data is collected. Nevertheless, when taking into account the average field trial duration in the EU of 2.6 years (Lheureux et al., 2003), it is evident that the negative trend found in annual EU notifications since 1999 does not exist to the same extent in the USA.

Figure 3: Number of field trials with GM plants in USA between 1987 and 2002



Source: APHIS, 2003

Like in the EU, field trials with GM plants are concentrated among a small number of firms and a limited number of crops in the USA. Three companies (Monsanto, Du Pont and Bayer Crop Science) accounted for 48 % of all trials and almost two thirds of the trials were carried out in maize, potato and soybean (Arundel, 2002b). 27.5 % of the US trials related to herbicide resistance, 41.6 % to pest resistance, 19.2 % to output traits for food or industrial purpose and the remaining 11.7 % to other categories like markers, fertility and agronomic traits (Arundel, 2002a). Among pest resistance 63 % related to insect resistance (mostly using the Bt gene), 21 % to virus resistance and around 12 % to fungi (Arundel, 2002b). Concerning the development over time, it can be observed that herbicide resistance had the dominant position with a proportion between 25 % and 30 % during the entire 1990s. Pest resistance traits also did not change their relevance significantly and had a share of around 40 % to 45 % of the total number of field trials. In contrast, there was a considerable decline in the share of field trials for food industrial purposes from around 30 % in 1995 to 17 % in 2001, while the share of technical agronomic field trials increased from 5 % in 1993 to 16 % in 2001 (Arundel, 2002a).

Since 1994 GM **varieties of 15 plants** have been **commercialised** worldwide. The big majority of product approvals concentrate on maize, oilseed rape, soybeans, cotton and potatoes, while only single GM products have been approved in other agricultural crops so far (AGBIOS, 2004). In terms of number of market approvals, maize represents the most important agricultural crop. The most important countries were USA and Canada where both 16 GM varieties of maize had been commercialised (AGBIOS, 2004), followed by Japan, Argentina and Australia (Lheuerux et al., 2003). Compared to other crops, a relatively broad range of companies have already commercialised GM products in maize including Monsanto, Pioneer Hi Bred, Bayer Crop Science, Syngenta Seeds, BASF and Dow Agro Sciences. These companies are active in USA as well mainly concentrating on herbicide-resistant and/or insect-resistant maize (AGBIOS, 2004).

Other cereals GM plants are commercially only available in rice and wheat: Bayer Crop Science commercialised one herbicide-resistant rice variety in the USA in 1999, while

Cyanamid Crop Protection did so for a herbicide-resistant wheat in Canada in 1998 (AGBIOS 2004). In addition, Monsanto announced the introduction of a GM Roundup Ready heart red spring wheat between 2003 and 2005 (AgraFood Biotech, 2002). After strong opposition of wheat importing countries as well as US wheat growers (fearing to loose competition on their major export markets), Monsanto announced to stop its commercialisation activities in herbicide resistant wheat in 2004 – except an approval of GM wheat at the US Food and Drug Administration (Rampton, 2004).

Another important crop in terms of commercialised GM products is oilseed rape of which 16 varieties had been commercialised globally (Lheureux et al., 2003). This relates in particular to Canada where solely 14 GM varieties had been brought to the market, indicating the high relevance of this country as producer of rapeseed. Until 2004 5 varieties of GM oilseed rape have been commercialised in the USA (AGBIOS, 2004) with three companies being active in this field (Bayer Crop Science, Monsanto, Pioneer Hi Bred). More than three quarters of the commercially available GM oilseed varieties in USA or Canada include herbicide resistance (against different herbicides), sometimes combined with male sterility (AGBIOS, 2004).

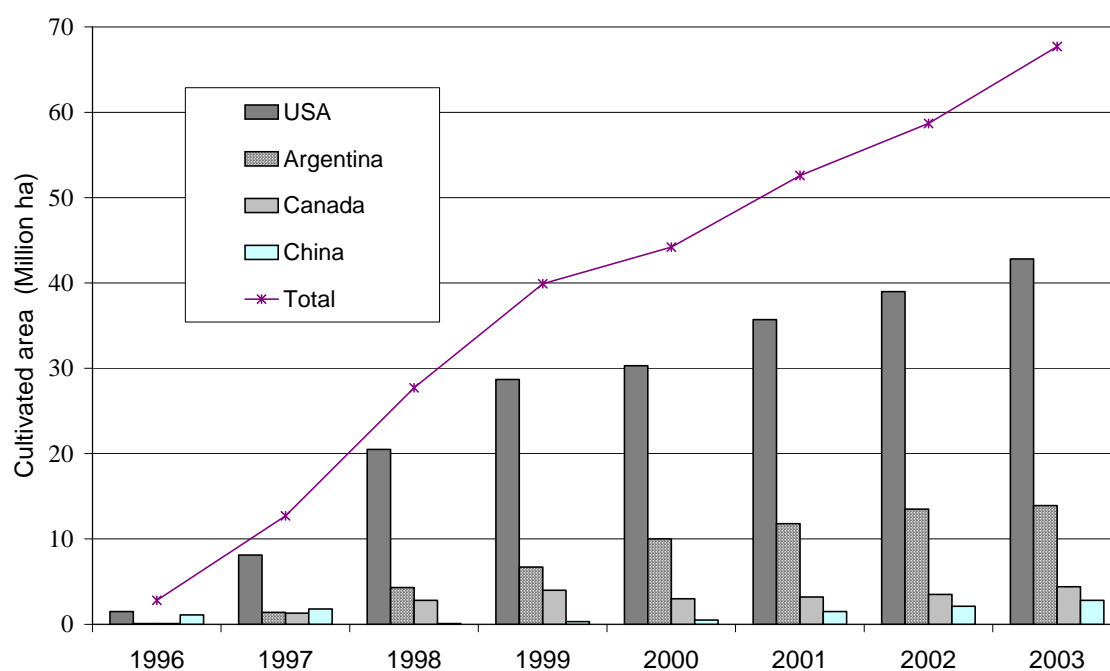
For soybeans which represent by far the most important crop in terms of cultivated area, eight GM varieties had been approved since 1994 globally. Most of them were commercialised in the USA, followed by Canada and Japan (AGBIOS, 2004). Concerning numbers of approved varieties in USA, Bayer Crop Science was the most important company, followed by Du Pont (AGBIOS, 2004) with herbicide resistance being the most important trait.

Since 1994, five GM varieties of cotton have been approved in overseas countries. This related in particular to the USA, Japan, Australia and Canada (Lheureux et al., 2003). This crop is dominated by Monsanto and its subsidiary Calgene which commercialised either insect-resistant or herbicide-resistant cotton in various countries. Monsanto also commercialised 4 GM varieties of potatoes mainly in the USA, Canada and Australia since 1994 including an insect resistance gene (Lheureux et al., 2003). In addition to these major

crops both with respect to cultivated area as well as number of approved GM products, such products have been commercialised in agricultural and horticultural crops like linseed, melon, papaya, squash, tomatoes, tobacco, carnation and chicory (Lheureux et al., 2003).

On a global basis transgenic crops are already cultivated to a high extent. A strong increase in the **area grown with GM plants** was registered in the last eight years. In 2003 67.7 million hectares were grown globally with transgenic plants (figure 4). 90 % of transgenic plants were cultivated in only three countries, namely USA, Argentina and Canada (James, 2003). In 2003 the main transgenic crops were soybeans (41.4 million hectares), corn (15.5 million hectares), cotton (7.2 million hectares) and rapeseed (3.6 million hectares) (James, 2003). With regard to the modified traits there is a strong dominance of herbicide-resistant plants which were cultivated on 73 % of the global area grown with GM plants. Insect-resistant plants were grown on 18 % of this area and combined herbicide- and insect-resistant plants on 8 % (James, 2003).

Figure 4: Cultivated area with GM plants 1996 to 2003



Sources: James, 2000, 2001, 2003, Menrad et al., 2003

Combining the results of the different studies, the impression arises that the de facto moratorium has had a negative impact on pre-market innovation activities related to GMOs in the EU. This relates in particular to SMEs which often have given up such projects due to their limited financial and personnel resources. In contrast to the situation in the EU, field trials with GMOs did not fall significantly in the USA in the last five years and a high number of mainly herbicide and/or insect resistant GM plants have been approved for commercial use in USA. With almost 43 million hectares in 2003 USA also has the world-wide leadership concerning commercial cultivation of GM plants (mainly soybeans, maize and cotton).

The EU regulatory framework adopted during the 1990s has played an important, largely negative role for the development of GMOs in the EU in the last decade. During this time period increased regulatory oversight in agro-food biotechnology coincided with growing negative public opinion and diminished trust in public authorities and regulatory agencies. In this context companies regarded the “constantly changing regulatory environment” as one major constraint for R&D and commercialisation of GMOs in the EU. In particular the practical handling of the existing regulations was strongly criticised as being too slow, bureaucratic and causing extraordinary costs. Politics was criticised for not taking any clear decision regards GMOs (which will form a reliable planning basis for the companies) and periodically intervening in the regulatory processes.

Combining the findings of Lheureux et al. (2003) with the analysis of the performance of scientific publications in different subfields of biotechnology (Reiss & Dominguez Lacasa, 2003) provides evidence, that the unclear legal situation with respect to the commercialisation of GMOs which emerged in the second half of the 1990s led to the cutting down of research activities in plant biotechnology which can be measured as decreasing scientific output. In more general terms, the unclear legal situation related to GMO on the commercial side seems to have a negative feedback on the science base. This could give reason for concern that once the legal environment would become more stable and/or more

favourable for commercialisation of GMOs, the EU knowledge base would be less prepared to provide the required know-how.

The “proof of principle” of the differing GMO-related regulatory approaches of USA and EU cannot be provided so far since no consumer or user reactions which are based on purchasing behaviour can be measured in the EU with regard to GM products. However, analyses of other innovative areas of food production and processing (e. g. Functional Food, organic agriculture and foods) indicate that even a strict, but clear regulatory framework has positive impacts on innovation parameters both in the EU and USA (Blind et al., 2003). In this sense, politics is asked to provide such a framework for agro-food biotechnology in the EU as well while industry should accept the critical view of many consumers with respect to genetic engineering and thus develop products which offer clear and obvious benefits to consumers. In addition, these products should be marketed with clear labels in order to ensure consumers’ freedom of choice.

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